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| 10/500,585   | 10/21/2004  | Xinghai Chen         | 1392/10/12 PCT/US   | 5246             |
| 25297 7590 07/14/2008<br>JENKINS, WILSON, TAYLOR & HUNT, P. A.<br>Suite 1200 UNIVERSITY TOWER<br>3100 TOWER BLVD.,<br>DURHAM, NC 27707 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| SMITH, CAROLYN L   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/500,585

**Applicant(s)**

CHEN ET AL.

**Examiner**

Carolyn L. Smith

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7, 8, 10-14, 16-22, 24, 25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 10-14, 16-22, 24, 25 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendments and remarks, filed 4/16/08, are acknowledged. Amended claims 1-3, 5, 7-8, 10-12, 14, 16-22, 24-25, and 27-29 and cancelled claims 6, 9, 15, 23, 26, and 30 are acknowledged.

Applicant's arguments, filed 4/16/08, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-5, 7-8, 10-14, 16-22, 24-25, and 27-29 are herein under examination.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 7-8, 10-14, 16-22, 24-25, and 27-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is maintained and reiterated for reasons of record.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that

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does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are drawn to a method, a computer readable medium comprising a method, a system comprising a method, and a computer system with modules that comprise a method. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be “useful,” the claim must produce a result that is specific and substantial. For a claim to be “concrete,” the process must have a result that is reproducible. For a claim to be “tangible,” the process must produce a real world result. Furthermore, the claims must be limited only to statutory embodiments.

In the instant case, claims 1-5, 7-8, 10-14, 16-22, 24-25, and 27-29 do not produce a tangible result. As currently recited, the methods in the claims may take place entirely within the confines of a computer without any communication to the outside world. A tangible requirement requires that the claim must set forth a practical application of the computational steps to produce a real-world result. Because the claims do not recite communication of a result in a tangible form to one performing the method, the claims are not statutory. This rejection

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could be overcome by amending the claims to recite that a result of the method is outputted to a display, or by including a physical transformation (provided there is adequate written support in the originally filed application).

This rejection is maintained because upon reconsideration, the requirements for satisfying the 35 USC 101 rejection have not been met. Outputting to a memory is insufficient in overcoming the rejection, because this output is not in a tangible form that is necessarily available to the user to be used. For example, outputting to an internal memory (i.e. RAM or ROM) is not actually an OUTPUT, of anything. The information is still entirely internal to the computer, where there is no indication that the information is ever intended to be communicated TO a user. In addition, outputting (generically) encompasses a carrier wave that is not tangible. It is also noted that the specific final result must be outputted (i.e. not merely outputting information in the middle of the method).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-8, 10-14, 16-22, 24-25, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

#### NEW MATTER

There does not appear to be adequate written support for the phrase “wherein the significance scores are outputted to a memory” (instant claims 1, 10, 18, 27, 28, 29). While there is written support for “output non-overlapping parameters” (Figure 2) and a computer system comprising output devices (page 5, second paragraph), there does not appear to be outputting to a memory which differs in scope.

Because the introduction of “wherein the significance scores are outputted to a memory” (instant claims 1, 10, 18, 27, 28, 29) does not appear to have adequate written support in the specification, claims, and/or drawings, as originally filed, this limitation is considered to be NEW MATTER. Claims 2-5, 7-8, 11-14, 16-17, 19-22, 24-25 are also rejected due to their dependency from claims 1, 10, and 18. This rejection is necessitated by amendment.

#### *Claim Rejections – 35 U.S.C. 112, First Paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

#### LACK OF ENABLEMENT

Claims 1-5, 7-8, 10-14, 16-22, 24-25, and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

This rejection is maintained and reiterated for reasons of record.

It is well known that the Human Genome Project has revealed that the number of human genes is in the range of 30,000. Even this number is controversial. Applicant's invention is directed to the assembling a distribution of gene expression level measurements, calculating a significance score, selecting measurements based on the score, comparing parameters between selected and non-selected measurements to determine the non-overlapping parameter from the selected gene expression measurements that is not present in the non-selected gene expression

measurements in order to infer function of one or more genes. It is also well known that a multitude of polymorphisms exists in human genes caused by environmental factors such as chemicals or cosmic rays. These complications result in an unpredictable length and difficulty in a research project that simply compares gene expression measurements between selected and non-selected gene expression level measurements to infer a function of genes. It is known that some genetic sequences are correlated with particular diseased individuals, but that each of these sequences was elucidated by lengthy research projects where the findings of the gene sequence was difficult and unpredictable. Thus, the simply comparing parameters of selected and non-selected gene expression levels as currently stated in the instant claims may not predictably result in gene function inference. It is possible that some of the gene expression measurements are “significant” due to experimental noise in the data or because they are from completely different organisms or genetic mutations completely unrelated to the genes function. Comparing the expression level data may find differences in the data, but one of skill in the art would not be able to infer the function of the gene without considerable additional research and even then such function determination is unpredictable. The publication of Doberstein et al. is cited regarding paragraphs 0003-0008 to support the numerous difficulties involved in relating gene sequences to other factors even utilizing modern bioinformatics tools. It is also noted one skilled in the art would not scientifically conclude that simply comparing genotypes results in inferring the function of a gene. Because of the undue experimentation necessary, the nature of the invention, the state of the prior art, the relative skill of those in the art, the unpredictability of the art, and the breadth of the claims, the instant claims are rejected due to a lack of enablement.



Applicant summarizes the Wands factors in making a determination as to whether an application meets the enablement requirements of 36 USC 112, 1<sup>st</sup> paragraph. Applicant argues that the claimed subject matter does not simply relate to comparing genotypes. It is noted that the Applicant's invention is directed to assembling a distribution of gene expression level measurements, calculating a significance score, selecting measurements based on the score, comparing parameters between selected and non-selected measurements to determine the non-overlapping parameter from the selected gene expression measurements that is not present in the non-selected gene expression measurements in order to infer function of one or more genes, as stated above. Applicant points out particulars of the invention that can be found in the specification. It is noted that this is a lack of enablement rejection, and not a lack of written description rejection. Applicant summarizes the instant invention. Applicant summarizes the Doberstein et al. reference. Applicant argues that the difficulties described by Doberstein et al. would not relate to the presently described methods wherein gene function is determined by comparing multiple gene expression data measurements for a single gene over a variety of parameters and determining which parameters are significant to gene expression. This statement is found unpersuasive as Doberstein et al. states that one can only speculate as to a possible function with bioinformatics tools and that "all informatics-predicted properties require experimental approval" (0004), in other words, further undue experimentation. Applicant argues that the specification describes a variety of techniques to overcome any problems relating to experimental noise. It is noted that while the specification may propose statistical methodology, such methodology is not recited or addressed in the instant claims. Applicant's arguments are deemed unpersuasive for the reasons given above.

***Claims Rejected Under 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 8, 11, 12, 17, 19, 20, 23, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 2 (line 1), 3 (lines 2-3), 8 (lines 1-2), 11, 12, 17, 19, 20, 23, and 25 recite the phrases “the gene expression level measurements” and “the expression level measurements” which lack clear antecedent basis as it is unclear if the measurements are referring to those from selected, non-selected, or both types. Clarification of this issue via clearer claim wording is requested. This rejection is maintained.

Applicant argues that amendments have provided sufficient antecedent basis. This statement is found unpersuasive as the issue still exists as described above.

***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 7-8, 10-12, 16-20, 24-25, and 27-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Van der Laan et al. (Biostatistics, December 2001, Vol. 2(4): pages 445-461). This rejection is maintained and reiterated for reasons of record.

Van der Laan et al. disclose a method of identifying genes and adding function annotations (inferring function) to genes from gene databases (abstract). Van der Laan et al. disclose using gene expression distribution with applied parameters (abstract) and for a given gene (i.e. gene  $j$  where  $j = 1$ ) under a variety of conditions, including healthy colon tissue and colon tumor tissue as well as single gene probabilities (page 446, fourth and fifth paragraphs; page 452, third and fourth paragraphs). Van der Laan et al. disclose finding means and covariances (abstract) which represent scores with significance. Van der Laan et al. disclose selecting a target subset of genes that are of biological interest based on statistics (scores) (abstract). Van der Laan et al. disclose estimating subsets of genes as well as their distribution and relevant measures (abstract). Van der Laan et al. disclose using clustering of subsets (abstract) which represents a comparison of subsets, target (selected) and not. Van der Laan et al. disclose sample means are within distance of the population mean and covariance (abstract) which represents a predefined distance/score. Van der Laan et al. disclose using a leukemia data

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set (abstract) which represents a genotype. Van der Laan et al. disclose comparing gene expression profiles across cells at different stages, in distinct pathological states, under different experimental conditions (page 446, second paragraph). Van der Laan et al. disclose comparing expression profiles from healthy cells and cancerous cells and learning which genes are over or under-expressed and studying differential gene expression that is associated with tumor suppression (page 446, second paragraph) and selecting and comparing genes from different expression distributions and post-screening based on dissimilarity information both within and across groups (Figure 2; page 458, last paragraph to page 460, second paragraph) which represents determining a non-overlapping parameter in selected gene expression level measurements not present in non-selected gene expression level measurements as well as a sorting of significant scores. Van der Laan et al. disclose searching for genes that are differentially expressed compared to a control and groups of genes that are substantially correlated with each other (page 447, second paragraph). Van der Laan et al. disclose only including genes closest to cluster centers (page 447, fifth paragraph) which represents a sorting based on significant scores of overlapped versus non-overlapped parameters. Van der Laan et al. disclose determining non-overlapping parameters in which the gene function inference is based (i.e. ALL/AML distinction) (i.e. select genes from different expression distributions and post-screening based on dissimilarity information both within and across groups (Figure 2; page 458, last paragraph to page 460, second paragraph). Van der Laan et al. disclose simulations (page 456, first paragraph) and methodology and software to handle such data (page 460, second paragraph) which represents a system and computer readable medium. Van der Laan et al. disclose use of an algorithm and models (page 460, fourth paragraph) and displayed/outputted

results (Figure 1, page 457 and Figure 2, page 459).

Thus, Van der Laan et al. anticipate the limitations in claims 1-3, 7-8, 10-12, 16-20, 24-25, and 27-29.

Applicant summarizes the amendments and argues that the claimed methods, systems, and computer readable medium relate to comparing multiple data measurements from the same gene (or biological molecule). This statement is found unpersuasive as the preamble of instant claim 1 recites "one or more genes" and while the assembling step recites "for a given gene", it does not preclude other genes. It is noted that Van der Laan et al. disclose and for a given gene (i.e. gene  $j$  where  $j = 1$ ) under a variety of conditions, including healthy colon tissue and colon tumor tissue as well as single gene probabilities (page 446, fourth and fifth paragraphs; page 452, third and fourth paragraphs). Applicant summarizes the invention and argues that Van der Laan et al. do not use varying expression of a particular gene or molecule under differing conditions to infer function on the basis of non-overlapping parameters. This statement is found unpersuasive as Van der Laan et al. disclose determining non-overlapping parameters in which the gene function inference is based (i.e. ALL/AML distinction) (i.e. select genes from different expression distributions and post-screening based on dissimilarity information both within and across groups (Figure 2; page 458, last paragraph to page 460, second paragraph). Applicant argues that independent and dependent claims are therefore distinguished from Van der Laan et al. This statement is found unpersuasive as Van der Laan et al. recite the limitations in claims 1-3, 7-8, 10-12, 16-20, 24-25, and 27-29, as described above.

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-8, 10-14, 16-22, 24-25, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van der Laan et al. (Biostatistics, December 2001, Vol. 2(4): pages 445-461) in view of Zhao et al. (US 2003/0219797). This rejection is maintained and reiterated for reasons of record.

Van der Laan et al. describe the limitations of instant claims 1-3, 7-8, 10-12, 16-20, 24-25, and 27-29 as described in the 35 USC 102 rejection above. Van der Laan et al. do not describe that the significance score is a z-score or that the z-score is greater than 3 and less than -3 (instant claims 4-5, 13-14, and 21-22).

Zhao et al. describe statistically analyzing large data arrays and using a significant z-score of 4.8 or higher (title, 0211, 0213, 0222) which is a significant z-score greater than 3, as stated in instant claims 4-5, 13-14, and 21-22.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use significant z-score values in the method of Van der Laan et al. where the motivation would have been to determine the goodness of fit between data by evaluating the statistical significance of the fit in order to extract useful and reliable information out of large data sets, as stated by Zhao et al. (abstract, 0003, 0017).

Thus, Van der Laan et al., in view of Zhao et al., make obvious the instant invention.

Applicant argues that Zhao et al. do not overcome the deficiencies of Van der Laan et al. This statement is found unpersuasive as Van der Laan et al. describe the limitations of instant claims 1-3, 7-8, 10-12, 16-20, 24-25, and 27-29 as described in the 35 USC 102 rejection above, and Zhao et al. describe the limitations in instant claims 4-5, 13-14, and 21-22. Applicant argues that the two references fail to teach various aspects of the recited claims. This statement is found unpersuasive as the combined references address all of the limitations as described above and Applicant's arguments are conclusory void of any factual support. Applicant's arguments are deemed unpersuasive for the reasons given above.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. If you have questions on access to the Private PAIR



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system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, please call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

July 7, 2008

/Carolyn Smith/  
Primary Examiner  
AU 1631